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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,441	03/01/2002	Bernhard O. Palsson	UCSD1330-2	6649
28213	7590	06/30/2005	EXAMINER	
DLA PIPER RUDNICK GRAY CARY US, LLP 4365 EXECUTIVE DRIVE SUITE 1100 SAN DIEGO, CA 92121-2133				ALLEN, MARIANNE P
ART UNIT		PAPER NUMBER		
		1631		

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/087,441	PALSSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Marianne P. Allen	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) 66-69 is/are withdrawn from consideration.
- 5) Claim(s) 71,72 and 74 is/are allowed.
- 6) Claim(s) 1-40,48-50,52-61,64-66 and 73 is/are rejected.
- 7) Claim(s) 41-47, 51, 62, 63, 70 is/are objected to.
- 8) Claim(s) 1-74 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

Applicant is advised that the responses filed 3/3/05 and 4/4/05 were ambiguous and inconsistent with respect to the claims under examination. The section on amendments to the claims requested cancellation of claims 1-16 and 44-67; however, the listing of claims included claims 1-73 (response filed 3/3/05) and claims 1-74 (response filed 4/4/05) as being pending. Page 13 of the response indicates that no claims have been added or amended; however, claims 41 and 71 were amended. It is presumed based on the arguments presented that claims 1-16 and 44-67 were not intended to be cancelled.

Applicant's arguments filed 4/4/05 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Election/Restrictions***

This application contains claims 67-69 drawn to an invention nonelected with traverse in the reply filed on 6/7/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

#### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The basis for the subject matter set forth in claims 12-13 and 46-47 is not seen.

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This objection is maintained for reasons of record. None of paragraphs [0033], [0038], [0135], and [0136], individually or collectively, disclose the concept of a data structure relating a plurality of reactions of a biochemical reaction network for reactions that occur in a first cell in a population in conjunction with a regulatory data structure that represents events that occur in a second cell in a population as required by the claims. Applicant's arguments are not understood.

***Claim Rejections - 35 USC § 101***

Claims 1-20 and 23-33 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

This rejection is maintained for reasons of record with respect to these claims.

Applicant argues that a computer readable medium is a thing and as such it is statutory subject matter. As set forth in the prior Office action, claiming nonfunctional descriptive material stored in a computer-readable medium does not make it statutory. *In re Sarkar*, 588 F.2d 1330, 1333, 200 USPQ 132, 137 (CCPA 1978).

It is maintained that the data structure of the claims does not impart functionality as written. Applicant argues that the claimed data structure consists of a physical or logical relationship among data elements because it expressly claims relating a plurality of reactant to a plurality of reactions and asserts that the claimed computer readable medium or media containing the recited data structure also impart functionality when employed as a computer component because it is used to determine a systemic property of the a biochemical reaction network. These arguments are not agreed with as there is nothing in the claim language with respect to any functionality. The "relating" as set forth in the claim is with respect to the nature of the data in the datastructure and not any functionality of the data structure with a computer.

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For example, a data structure with three fields (e.g. type of reaction, reactant or substrate of that reaction, product of that reaction) does not speak to any computer functionality. Claim 1 has no requirement that the data structure of (a) and the constraint set of (b) be capable of interacting (individually or collectively) with a computer in execution of any method. Note that the claims at issue in *In re Lowry*, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994) were directed to a “memory for storing data for access by an application program being executed on a data processing system” with specific recitation of the “data structure including information resident in a database used by said application program.” These limitations imparted the necessary functionality. Such limitations are not present in the instant claims. All the instant claims require is computer readable medium or media comprising a data structure per se and a constraint set (interpreted as being data). This is non-statutory.

Applicant’s argument on page 20 of the response that the “constraint function” of claim 14 correlates an outcome of a regulatory event with a variable constraint is noted but the claim does not require that this function be in the context of a computer program or software that is in executable form. Likewise, as set forth in the prior office action, the commands in claims 17 and 25 are not required to be in the context of a computer program or software that is in executable form.

This rejection has been withdrawn with respect to claims 21-22. Upon further consideration, the requirement for a user interface is considered to impart functionality to the computer readable medium or media.

***Claim Rejections - 35 USC § 112***

Claims 1-33 are directed at computer readable medium or media comprising a data structure and a constraint set and were considered unclear from the claim how the data structure and constraint set are related to each other and the computer readable media. Applicant's response does not explain or clarify how the data structure and constraint set are related to each other and the computer readable media or medium. However, in view of applicant's arguments, this rejection has been withdrawn. The claims are considered to encompass embodiments such as where the data structure is on one disk and the constraint set on another and multiple copies of a disk containing the same data structure and constraint set. The data structure and constraint set are not considered to interact with each other or the computer for the reasons set forth in the rejection under 35 USC 101.

Claims 2-7, 9-16, 26-30, 32-33, 35-39, 48-50, 52, 55, 64-66, and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-7, 26-30, and 32-33 are confusing and do not appear to limit the computer readable medium or media of claim 1 and claims 9-13 do not appear to limit the computer readable medium or media of claim 8. Applicant's response does not explain or clarify how the scope of the claims differ and the dependent claims further limit the preceding claim. In fact, applicant responds by "not conceding that the rejected dependent claims do or do not alter the structure of the claimed data structure or constraint set" (see response at page 18). If they do not further limit the claims then the claims are not properly dependent as they fail to provide a

further limitation. Again as an example, the data structure embraced by claim 1 would not differ whether the reactant is identified as a product is insulin or nerve growth factor. Similarly, the regulatory data structure of claim 8 does not change whether or not the regulatory event is or is not due to a signal transduction pathway. This information would be stored in the same way and does not require a change to the data structure. Applicant is requested to identify what the new element to the data structures or constraint sets are.

Claim 14 remains confusing for reasons of record. Applicant refers to paragraph [0074] and Figure 3. However, this particular embodiment is not a limiting definition with respect to the claims. In addition, Figure 3 is a schematic drawing illustrating an example regulatory network for a reaction. This portion of the specification does not speak to what was intended to be present on a computer readable medium or media to meet the limitation of a constraint function. Figure 3 illustrates a model and perhaps process or method steps related to the model. Again, if an executable instruction or command was intended, it is unclear if this is a program separate from the data structure and constraint set on the computer readable medium or media of claim 1.

Claim 30 remains confusing a reciting a “confidence rating.” The claim does not make clear what this rating refers to. Applicant refers to paragraph [0040] and the disclosure that it indicates a level of confidence with which a reaction is believed to occur in a particular biochemical reaction network or organism. The claim has no requirement that the confidence rating is with respect to the belief that a reaction occurs in a particular biochemical reaction network or organism. Applicant is improperly reading limitations from the specification into the claims.

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Claims 35-39 remain unclear for reasons of record. Applicant refers to paragraphs [0033] and [0049]; however, these paragraphs do not speak to method steps as recited and the claims are not limited as argued by applicant.

Claim 48-50 and 52 remain confusing for reasons of record. Applicant refers to paragraph [0049]. However, this does not make clear in the claim that this correlation is performed and that the information generated is used in some way by the method of claim 41. As written, the claim appears to be directed to a method with a constraint function capability and it is unclear whether or not that capability is used. Note that claim 51 was not part of this rejection in the prior Office action because it clearly indicates that the constraint function is used to correlate.

Claim 55 remain confusing in reciting “modifying” the data structure and/or constraint set. Applicant points to paragraph [0037]; however, the claim is not limited to a format manipulation. Applicant also points to paragraph [0032]-[0033] and [0047]-[0048] with respect to values being modified; however, the claim is not limited to these changes. The claim does not make clear what aspect of the constraint set or data structure is intended to be modified.

Claims 64-66 remain confusing for reasons of record. The method of claim 64 provides a gene database with particular information. The claim does not require that this database be used in any capacity. “Relating” in claim 64 is not an action. It is a description of what is present in the database. This claim language does not set forth a step to include the information from the gene database in the data structure which is then analyzed in keeping with the method of claim 34 as appears to be argued by applicant.

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Claim 73 remains confusing in reciting "change in an environmental condition." Claim 71 does not contain any such conditions. The variable of claim 71 is not required to be related to an environmental condition.

Applicant is entitled to only the instant filing date of 3/1/02 and not the filing dates of either provisional applications 60/272,754 (filed 3/1/01) or 60/323028 (filed 9/14/01). The invention as set forth in the present claims is not disclosed in either provisional application. Computer readable medium or media with the limitations as set forth in the claims are not disclosed. Methods with the particular steps and requirements as set forth in the claims are not disclosed.

Applicant has not pointed out where the claimed computer readable media and methods are disclosed in any of the provisional applications and it is not apparent. These provisional applications do not parallel or correspond to the instant specification in terms of their disclosure. They do not set forth statements with respect to the metes and bounds of the contemplated invention, definitions of terms, particular embodiments, and so forth that define the invention set forth by the instant claims.

***Claim Rejections - 35 USC § 102***

Claims 1-3, 5-7, 17-20, 23-26, 29, 32-34, 40, 53-54, 56-61, and 64-66 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/46405 (10 August 2000).

This rejection is maintained for reasons of record.

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In response to applicant's arguments, regulated reactions and variable constraints within the meaning of the claims are disclosed by the prior art. At least page 3, lines 15-36, and page 7, lines 19-27, disclose limiting constraints on various fluxes (meaning the constraints are variable and the reactions they are related to are regulated). The invention is embodied in a software application. The systemic property of a biochemical reaction network determined by the prior art is at least one flux distribution that minimizes or maximizes said objective function when the constraints are applied to the data structure (see at least page 7, line 20, through page 8, line 33) as required by the method of instant claim 34.

***Claim Rejections - 35 USC § 103***

Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (Journal of Biological Chemistry, June 1999).

This rejection is maintained for reasons of record.

Applicant's arguments with respect to Edwards et al. not teaching a method of determining a systemic property of a biochemical reaction network are not germane as no method claims have been rejected. The structural elements required by the claims are taught by Edwards et al. The difference between the prior art and the claimed invention is the information. This information is descriptive information stored on computer readable media. Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. See MPEP 2106.

***Conclusion***

Claims 41-47, 51, 62, 63, and 70 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 71, 72, and 74 are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Marianne P. Allen*  
Marianne P. Allen  
Primary Examiner  
Art Unit 1631      *6/24/05*

mpa